REMARKS

Claims 13 and 18 have been amended and claim 22 added. Claims 13-22 are pending. Counsel for the Applicants thanks Examiner Weiss for the courtesy extended during the phone conference to discuss the prior art and pending claims prior to the issuance of the outstanding office action. As a result of the phone conference, a better understanding of the Examiner's position was obtained, which facilitated the preparation of this response establishing that the cited Palleni patent (U.S. Patent 3,964,476) does not teach or suggest the claimed inventions, and in fact teaches away.

Palleni Does Not Disclose the Claimed Inventions and Teaches Away

It is respectfully submitted that Palleni does not teach or suggest a multilumen proximal fitting for a unilimb multilumen breathing circuit as claimed. Palleni's invention is directed to providing pulsed positive and negative pressure to a patient's respiratory system. At the proximal end of Palleni is an inlet valve and coupling unit 26 as shown in Figure 4 and the left side of Figure 5. In contrast to the present invention, Palleni's coupling unit 26 does not provide fresh inspiratory gas to a patient via one conduit and exhaust expiratory gases via another conduit. Fresh inspiratory gases are carried via flexible tubing from unit 26 to a distal outlet valve unit 28 at the patient end, which contains pressure controlled valves 70 and 72 that force exhaust out at the patient end via outlet 68 (see sentence bridging columns 5 and 6). With regard to flexible inner tube 32, valve 40 at the machine end further bars any exhaust gas in tube 32 from returning to the machine end (see column 6, lines 60-64). Hence, Palleni does provide a circuit as exhaust gases are not circulated back to the machine.

The flexible tubes 30 and 32 of Palleni are directly attached to the proximal coupling unit 26; Palleni states at column 5, lines 29-20, "the inlet portion of the outer tubular member 30 **is secured**." Thus, Palleni does not teach or suggest a proximal fitting for detachably connecting the inner and outer tubes to a proximal terminal. Further, Palleni does not teach a proximal terminal as that term is defined in the present application and generally understood in the art. However, assuming for the sake of argument only that Palleni's unit 26 is analogous to a proximal terminal, the prior art

teaches away from making a proximal terminal detachable from the flexible tubing attached thereto, and Palleni contains no teaching or suggestion to make the tubing detachable.

Palleni issued in 1976, based on an application filed in 1973. Since before Palleni and up until the present invention in 1996, the prior art has generated multiple teachings that the proximal ends of tubing forming unilimb respiratory conduits need to be fixedly attached and bonded. Examples of prior art patents that teach away from an independent proximal terminal in multilumen unilimb breathing circuits include U.S. Patent 3,856,051, U.S. Patent 4,007,737, and U.S. Patent 4,265,235 (to Dr. Atsuo Fukunaga, the present inventor), and U.S. Patent 4,637,384. These patents contain numerous teachings of why it was considered necessary to firmly attach the flexible patient respiratory conduits at the machine end. For example, U.S. Patent 4,367,769, to Bain, at column 1, lines 38-52, states:

> It is the fact of this connection [i.e., machine adaptor or proximal terminal] that has proved to be a considerable problem...The second flexible tube [i.e., fresh gas carrying inner tube] connected to the elbow has on occasion become disengaged whereby the anesthetic gas spills into the confines of the first flexible tubular member [i.e., the outer tube] to the detriment of the patient. Due to the fact that the connection to the elbow with the second flexible tubular member is internally with respect to the rigid tubular connector, one cannot visually inspect the device to determine whether the aforementioned internal connection is still in engagement.

Therefore, those of skill in art concluded that it was necessary to carefully bond all of the components of a respiratory circuit together, i.e., the machine adaptor was bonded to the flexible conduits running to the patient.

U.S. Patent 4,637,384, to Schroeder, column 1, lines 23-37, states:

> One difficulty with the coaxial circuit, particularly in anesthesia breathing circuits, is the assurance of the integrity of the inhalation circuit. Since the inner tube carries fresh gas to the patient or, in the case of an anesthesia circuit, the anesthetic with fresh gas, it is extremely important for the attending personnel to be immediately aware of an inadvertent disconnection.
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> At the machine end, a disconnection of the inner tube can escape immediate attention, since its view is shielded by the surrounding corrugated outer tube. Thus, it is possible for the inner tube to be

disconnected, yet the overall coaxial circuit has the appearance of being completely intact. The potentially dangerous situation of rebreathing exhaled gases is created, which can result in hypoxia and CO_2 buildup in the patient.

Other prior art teachings reinforced the concept that respiratory conduits need to be firmly connected at the proximal end of a circuit. For example, Hannallah et al, assigned reference number A49 in the Information Disclosure Statement submitted August 15, 2002, reported the hazards associated with disconnection of the respiratory conduit from the machine end connector. See also U.S. Patent No. 3,856,051 to Bain and U.S. Patent No. 4,265,235 to Fukunaga (the present inventor). Hence, Palleni's disclosure is consistent with the prior art teaching away by showing the proximal ends of the tubes directly connected to the proximal unit 26.

In contrast, the proximal fitting of the present invention enables a flexible multilumen breathing conduit to be readily attached and detached to a proximal terminal of the present inventions by a user at the site of use with a simple one-handed motion. This is not taught or suggested by Palleni. In view of the great advantages of the present inventions and 20 years passage of time since Palleni issued, it is clear that Palleni does not teach nor make obvious the present inventions.

Further, Palleni's device operates in such a completely different way that one of skill in the art would not modify or apply its teachings to unilimb circuits carrying inspiratory gas to a patient in one lumen and expiratory gases from the patient to an exhaust conduit at the machine via a second lumen. Such unilimb circuits are designed to circulate exhaled gases back to the machine, a function which Palleni is designed to defeat. Hence, Palleni teaches away from the present invention.

It was not until the present inventions were invented and publicized that those of skill in the art recognized the substantial benefits of a unilimb multilumen proximal fitting that is attachable and detachable to a mating multilumen proximal terminal to form a unilimb circuit, such as improved safety with a simpler and less expensive device. As seen from the prior art, prior to the present inventions, it was believed that detachability of the respiratory conduits from the rest of the circuit was extremely unsafe. The present inventions have achieved commercial success, demonstrated by the previously submitted Declaration under 37 CFR 1.132 of Kevin Burrow, the Vice President of the

Licensee, King Systems. The substantial benefits of the present inventions and the associated commercial success demonstrate that one of ordinary skill in the art could not reasonably interpret the Palleni patent to teach or suggest the claimed inventions.

Therefore, it is respectfully requested that the rejections based on Palleni be withdrawn.

Claims 15 and 16 are rejected as obvious over Palleni in view of U.S. Patent 5,715,815 to Lorenzen ("Lorenzen"). It is respectfully submitted that these rejections are moot in view of the arguments above. Further, there is no teaching or suggestion to combine Lorenzen with Palleni, and it is respectfully submitted that such a combination would still not result in the present inventions.

In view of the foregoing, it is respectfully submitted that claims 13-22 are in condition for allowance and allowance is respectfully requested. It is also respectfully requested that the Examiner telephone the undersigned with any questions or concerns about the application so that further prosecution can be expedited.

Respectfully submitted,

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Date

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